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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,006	09/20/2001	Charles Young	07039-346001	2450

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FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/957,006

Applicant(s)
Young

Examiner
Randall Winston

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 2, and 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 and 6 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group II of claims 3-11 in Paper No. 8 is acknowledged. The traversal is on the grounds that applicant argues that a composition comprising POH, irrespective of what else is included in the composition would be encompassed in a single search. The claims assigned to Groups IV, V, and VI in the Restriction Requirement should be combined into a single group.

Applicants' argument is not found persuasive because, as the Examiner explained in the Restriction Requirement (Paper No. 7), Inventions IV, V, and VI are distinct from elected Invention II because the inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These claimed method, Inventions II, is distinguishable from the three different claimed composition because they are unrelated compositions and/or an unrelated method. Inventions II is drawn to a method of treating prostate cancer etc. whereas Invention II's method utilizes different steps and approaches to achieve its preamble objective than the three different composition comprising of different active ingredients. Inventions IV-VI are each drawn to three different compositions. The three compositions are either a composition comprising perillyl alcohol and one or more compounds or a composition comprising perillyl alcohol or a composition comprising perillyl alcohol and a packaging material). Therefore, these inventions are distinct since they are not disclosed as capable of use together, they have different modes of operation, they have different functions,

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and/or they have different effects. In addition, one would not have to practice the method and/or use the various compositions at the same time to practice just one method alone and/or one composition alone.

The restriction requirement is still deemed proper and is therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 7 and 10 recite the terms "derivative of." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning "derivative thereof." There is no definition of "derivative thereof" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Therefore, applicant may overcome this rejection by clearly delineating the metes and bonds of what is "derivative thereof."

Claims 9 is made vague in indefinite by the term "prostatectomy." Applicant may overcome this rejection by providing the correct spelling of the term.

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All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imagawa et al. (US 6133324).

Applicant claims a method of treating an individual with prostate cancer and/or BPH (note: see, the specification on page 1 line 26 states BPH is related to prostate cancer) or at risk of developing prostate cancer or reducing the risk of recurrence of prostate cancer via administering a dose of perilly alcohol (POH) or a derivative thereof (?) to said individual (i.e. human).

Imagawa et al. teach that perilly alcohol and derivative thereof have been demonstrated to provide beneficial anti-cancer effects in a patient when administered (see, e.g. column 1 lines 57-65). Imagawa et al. do not expressly disclose using perilly alcohol for treating prostate cancer and/or precancerous prostate cancer conditions (i.e. BPH).

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However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat prostate cancer and/or prostate precancerous conditions (i.e. BPH) by administering a result-effective amount of perillyl alcohol to a patient having prostate cancer and/or precancerous BPH based upon the beneficial teachings provided by Imagawa with respect the proven anti-cancer activity perillyl alcohol provides *in vivo*. Please note that the underlying functional effects instantly claimed (i.e. inhibiting the transactivating ability of an androgen receptor) would be intrinsic upon administration of an anti-cancer effective amount of perillyl alcohol to such a patient.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imagawa et al. (US 6133324) in view of Shyjan et al. (US 6355430).

Applicant claims a method of treating an individual with prostate cancer and/or BPH (note: see, the specification on page 1 line 26 states BPH is related to prostate cancer) or at risk of developing prostate cancer or reducing the risk of recurrence of prostate cancer via administering a dose (i.e. utilizing different methods of administering) of perillyl alcohol (POH) or a derivative thereof (?) to said individual (i.e. human) and monitoring the transactivating ability of said androgen receptor in said individual.

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Imagawa et al. teach that perillyl alcohol and derivative thereof have been demonstrated to provide beneficial anti-cancer effects in a patient when administered (see, e.g. column 1 lines 57-65). Imagwa et al. do not expressly disclose using perillyl alcohol for treating prostate cancer and/or precancerous prostate cancer conditions (i.e. BPH), monitoring the transactivating ability of said androgen receptor, and how perillyl alcohol is administered.

Shyjan et al. beneficially teach administering an anti-androgen agent to cultured prostate cancer cells to serve as a marker for monitoring the transactivating ability of an androgen receptor for treating of prostate cancer. (see, e.g. column 1 lines 66-67, column 2 lines 1-11 and column 2 lines 36-43)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention to modify the teachings taught by Imagawa et al.'s with respects to the proven anti-cancer activity perillyl alcohol provides when administered *in vivo* to an individual (see,e.g. 103a explanation above) to include the beneficial teachings taught by Shyjan et al.of administering an anti-androgen agent (i.e. perillyl alcohol) to cultured prostate cells to serve as a marker for monitoring the transactivating ability of an androgen receptor for the treatment of prostate cancer in an individual whereas both combined teaching would obtained an improved claimed invention method of treating prostate cancer and/or prostate precancerous conditions (i.e BPH) in an individual. Furthermore, one of ordinary skill in the art would have been motivated to include the adjustment of other conventional working conditions such as (e.g. the effective dose of perillyl alcohol and how perillyl alcohol is administered), because these conventional working conditions

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are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Moreover, the art recognizes functional or mechanical equivalency of a claimed compound/element with that of the prior art compound/element provides a *prima facie* case of obviousness for the skilled artisan to interchangeably substitute one equivalent for the other (see, e.g. MPEP 2144.06) within a preparation (i.e. the substitution of anti-androgen agents to monitor the transactivating ability of an androgen receptor for the treatment of prostate cancer).

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER